K081580

JUN 19 2008




## 510(k) Summary of Safety and Effectiveness

1. **Sponsor Name:** ConMed Endoscopic Technologies, Inc.
129 Concord Road
Billerica, MA 01821
Telephone: 978-964-4232
Contact Individual: Karen Provencher
Sr. Regulatory Affairs Specialist

2. **Device Name:** ConMed Beamer™ Argon Snare Probe

3. **Identification of Predicate or Legally Marketed Device:**
ConMed Optimizer Snare cleared under K820430 on April 8, 1982
Olympus SD Electrosurgical Snare cleared under K902735 on August 2, 1990
ConMed ABC Probes for Flexible Endoscopes cleared in K990586 on May 17, 1999
ERBE Argon Plasma Coagulator cleared in K013348 on October 26, 2001

4. **Device Description:**
The Beamer Argon Snare Probe is used in conjunction with the Beamer system generator for the delivery of gas and electrosurgical current through a flexible endoscope to an electrode wire snare at the operative site.

The Beamer Snare Probe consists of connectors for attachment to the output of an Argon Beam Coagulation Unit. The device also consists of catheter tubing for delivering argon gas to the operative site within the patient, as well as an internal wire to carry high frequency (HF) electrosurgical current to the electrosurgical snare. The snare probe device is provided in two lengths 160 cm and 230 cm for use in flexible bronchoscopes, gastroscopes, colonoscopes and duodenoscopes.

The electrosurgical snare is provided in a symmetrical loop (braided or monofilament oval) in sizes of 15mm and 30mm and can be positioned back into the catheter tube, such that it does not contact the patient's tissue during the argon beam coagulation procedure.

The Beamer Argon Snare Probe consists of a stainless steel wire that extends from the probe connector to the distal end of the probe. The

proximal end of the stainless steel wire is locked into the connector body. The distal end of the wire is soldered to a snare shaped wire located at the distal end of the probe. In its retracted position the snare wire is in electric contact to a tungsten electrode. The distal end of the Beamer Probe has a ceramic tip which provides a thermal insulation barrier for the tubing to prevent heat degradation during coagulation. The tungsten electrode remains recessed in the ceramic tip such that there is no tissue contact during the argon beam coagulation procedure.

There are five configurations of the Beamer Argon Snare Probe. The probes vary in length and loop configuration to accommodate the procedure performed by the physician. The Beamer Argon Snare Probes are provided sterile by ethylene oxide and are single use only.

5. **Intended Use:**
The Beamer Argon Snare Probe is used in conjunction with the Beamer system generator for the delivery of gas and electrosurgical current through a flexible endoscope to an electrode wire snare at the operative site.

6. **Comparison of Technological Characteristics:**
The Beamer Snare Probes are substantially equivalent to the predicate devices both in intended use, technological characteristics and materials.

7. **Performance Testing:**
Biocompatibility and bench testing have been performed to demonstrate equivalence of the Beamer Argon Snare Probes to their predicate devices. All testing passed the predetermined performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

ConMed Corporation
% Intertek Testing Services
Mr. Daniel W. Lehtonen
Senior Staff Engineer-Medical Devices
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K081580
Trade/Device Name: Beamer™ Argon Snare Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 03, 2008
Received: June 05, 2008

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## C. INDICATION FOR USE

510(k) Number (if known) K081580

**Device Name:** Beamer™ Argon Snare Probe

**Indication for Use:**

The Beamer Argon Snare Probe is used in conjunction with the Beamer system generator for the delivery of gas and electrosurgical current through a flexible endoscope to an electrode wire snare at the operative site.

Prescription Use X AND/OR Over the Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MKM

**(Division Sign-Off)**
**Division of General, Restorative,**
**and Neurological Devices**



**510(k) Number** K081580